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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,566	03/28/2005	Ralph A Stearns	2772 (203-3099)	9153

Covidien  
60 Middletown Avenue  
North Haven, CT 06473

7590

01/27/2009

EXAMINER
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DUFOUR, DEVANIE A

ART UNIT	PAPER NUMBER
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4115

MAIL DATE	DELIVERY MODE
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/529,566	<b>Applicant(s)</b> STEARNS ET AL.	
	<b>Examiner</b> DEVANIE DUFOUR	<b>Art Unit</b> 4115	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 3,5-8,15-19,22,23,29-41,43,46 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,9-14,20,21,24-28,42,44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/16/2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-28, 42-47, drawn to a retractor with a shaft having at least one section and a cable.

Group II, claim(s) 29-35, drawn to a retractor with a shaft and a plurality of finger elements.

Group III, claim(s) 36-41, drawn to a retractor fabricated from a shape memory substance and a bore that receives temperature changing medium.

2. The inventions are distinct, each from the other because of the following reasons:

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The retractor of each of the three groups has unique structural elements. The inventions as claimed are not capable of use together and have materially different designs. The special technical features found only in Group 1 are the mechanical interfaces that connect the first and second sections. The special technical features found only in Group 2 are the plurality of fingers and the bundle of cords that extend between the

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finger elements. The special technical features found only in Group 3 are the temperature changing medium and the shape memory substance which the shaft is fabricated.

3. In addition, if the applicant elects invention I above, the applicant must further elect between species. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The species of mechanical interfaces are as follows:

Species a) Fig. 1D;

Species b) Fig. 1G;

Species c) Fig. 1J;

Species d) Fig. 2A;

Species e) Fig. 3A.

The species of cables are as follows:

Species 1) Fig. 1E;

Species 2) Fig. 1F.

Applicant is required, in reply to this action, to elect a single species of mechanical interfaces and cables to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species a) Fig. 1D, Claims 5, 15, 16, 43;

Species b) Fig. 1G, Claims 3, 18, 19;

Species c) Fig. 1J, Claims 24;

Species d) Fig. 2A, Claims 6, 8, 22, 46;

Species e) Fig. 3A, Claims 7, 23, 47.

The species of cables are as follows:

Species 1) Fig. 1E, Claims 1-16, 18-28, 42-47;

Species 2) Fig. 1F, Claim 17.

The following claim(s) are generic: For the species of mechanical interfaces, claims 1, 2, 4, 9-14, 17, 20, 21, 25-28, 42, 44 and 45 are generic; and for the species of cables, no claims are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The mechanical interfaces all have materially different designs; and the cables also have materially different designs.

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4. During a telephone conversation with Ms. Kimberly Perry (applicant's attorney) on January 13, 2009 a provisional election was made with traverse to prosecute the invention of Group 1, claims 1-28 and 42-47, Species c and Species 1. Affirmation of this election must be made by applicant in replying to this Office action. Claims 3, 5-8, 15-19, 22, 23, 29-41, 43, 46 and 47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 2, 4, 9-14, 20, 21, 24-28, 42, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kieturakis (U.S. Patent Number 6,067,990).

Regarding claim 1, Fig. 3 of Kieturakis discloses a retractor (5) for use through a trocar port comprising: a shaft (12) having at least a first section (21) having a first mechanical interface (i.e. proximal planar abutment face 41a of element 21 is angled with respect to axis) and a second section (22) having a second mechanical interface (i.e. angled distal planar abutment face 41b of articulating element 22) for engaging the first mechanical interface (column 4, lines 17-20), the first section and second section being selectively movable from a first generally longitudinally-aligned configuration along an axis defined through the shaft (16) and the first mechanical interface is disengaged from the second mechanical interface (as shown

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by Fig. 3), to a second configuration wherein the second section is disposed at an angle relative to a longitudinal axis of the shaft (as shown by Fig. 4) and the first mechanical interface is engaged with the second mechanical interface (i.e. 41a abuts against 41b); and at least one cable (27a and 27b) extending through the shaft and being operatively secured to the second section (i.e. fixed in tip), the cable being remotely actuatable to move the second section from the first to the second configuration upon selective translation of the cable (i.e. capable of being deformed, column 1, lines 55-67).

Regarding claim 2, Fig. 3 of Kieturakis discloses the first (21) and second mechanical (22) interfaces cooperate to align the first section and the second section (i.e. via abutment faces) and engage the first and second sections with one another upon movement from the first configuration to the second configuration (column 4, lines 17-20).

Regarding claim 4, Fig. 6 of Kieturakis discloses the shaft (12) includes an outer sleeve (18) which houses the first and second sections.

Regarding claim 9, Figs. 3, 4 and 6 of Kieturakis discloses an organ retractor (5) comprising: a tube (18) having a lumen extending there through and defining a longitudinal axis (16); and a distal section (22), an intermediate section (21) and a proximal section (i.e. another segment unlabeled near proximal end of retractor, as shown in Fig. 3) disposed within the lumen of the tube, wherein the retractor has a first configuration in which the distal, intermediate and proximal sections are substantially aligned with the longitudinal axis and disassociated with one another (as shown in Fig. 3), and at least one second configuration in which the intermediate section and the distal section are engaged with one another so that the distal section is disposed at an angle with respect to the longitudinal axis (as shown in Fig. 4).

Regarding claim 10, Fig. 3 of Kieturakis discloses a first cable (27a) extending through the proximal section and the intermediate section, and operatively secured to the distal section (i.e. fixed in tip), wherein translation of the first cable in a proximal direction causes the distal section (22) to operatively engage the intermediate section (21) at an angle relative to the longitudinal axis (as shown in Fig. 4).

Regarding claim 11, Fig. 3 of Kieturakis discloses a second cable (27b) extending through the proximal section and operatively secured to the intermediate section, wherein translation of at least one of the first and second cables in a proximal direction causes the intermediate section (21) to operatively engage the proximal section (as shown in Fig. 4).

Regarding claim 12, Fig. 3 of Kieturakis discloses the distal section (22) includes at least one first mechanical interface (41b) formed at a proximal end thereof and the intermediate section (21) includes at least one second mechanical interface (41a) formed on a side surface thereof, the second mechanical interface being complementary with the first mechanical interface (i.e. abutment faces), wherein when the distal and intermediate sections engage one another (column 4, lines 17-20), the first mechanical interface and the second mechanical interface maintain the distal section at an angle with respect to the longitudinal axis (as shown in Fig. 4).

Regarding claim 13 Fig. 3 of Kieturakis discloses the proximal section (i.e. another segment unlabeled near proximal end of retractor, as shown on Fig. 3) includes at least one third mechanical interface (i.e. angled abutment face) to formed at a distal end thereof and the intermediate section (21) includes at least one fourth mechanical interface formed at a proximal end thereof (angled abutment face), the fourth mechanical interface being complementary to the third mechanical interface (i.e. allows segment 21 to abut against unlabeled proximal segments),



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wherein when the proximal and intermediate sections engage one another, the third mechanical interface and the fourth mechanical interface maintain the proximal and intermediate sections substantially aligned with the longitudinal axis (as shown in Fig. 4).

Regarding claim 14, Fig. 3 of Kieturakis discloses the proximal section includes at least one longitudinally oriented passage (26a and 26b) extending there through, wherein the first and the second cables (27a and 27b) extend through the at least one longitudinal passage.

Regarding claim 20, Fig. 6 of Kieturakis the tube is fabricated from a flexible material (column 4, lines 44-46).

Regarding claim 21, Fig. 3 of Kieturakis discloses an organ retractor (5) comprising an elongated shaft (12) defining a longitudinal axis, the shaft having a first section (21) and a second section (22) pivotably connected to one another; and a first cable (27a) extending through the first section and operatively connected to the second section for manipulating the retractor from a first configuration (as shown by Fig. 3) to at least one second configuration (as shown in Fig. 4), wherein in the first configuration the first and second sections are substantially aligned with the longitudinal axis and in the at least one second configuration the second section is at an angle with respect to the longitudinal axis.

Regarding claim 24, Fig. 3 of Kieturakis discloses the first section (21) has a distal surface (41a) and the second section (22) has a proximal surface (41b), the distal surface comprising an angled surface that faces the proximal surface of the second section.

Regarding claim 25, Fig. 6 of Kieturakis discloses a film (18) extending between the first and second sections.

Regarding claim 26, Fig. 3 of Kieturakis discloses at least one stop member (i.e. angled surfaces 41a and 41b act as a stop to prevent further curvature) provided on at least one of the distal surface and the proximal surface.

Regarding claim 27, Fig. 3 of Kieturakis discloses a third section (unlabeled section located in the distal region 14) pivotably connected to the second section (22); and a second cable (27b) extending through the first section and the second section and operatively connected to the third section for manipulating the retractor from the first configuration (as shown in Fig. 3) to the at least one second configuration (as shown in Fig. 4).

Regarding claim 28, Fig. 3 of Kieturakis discloses a first mechanical interface (41a) provided on the first section (21), a second mechanical interface provided (41b) on the second section (22) for engaging the first mechanical interface, a third mechanical interface (i.e. angled side opposite 41b) provided on the second section (22), and a fourth mechanical interface (abutment face on an unlabeled section located in the distal region 14) on the third section (unlabeled section located in distal region 14) for engaging the third mechanical interface (as shown in Fig. 4).

Regarding claim 42, Fig. 3 of Kieturakis discloses a retractor comprising: a plurality of sections (21 and 22) defining a shaft (12), each of the sections having a mechanical interface (i.e. abutment face) for engaging an adjacent section, each section having a first position in longitudinal alignment with an adjacent section (as shown in Fig. 3) and a second position offset from the first position so that the sections form a substantially closed shape for engaging tissue (as shown in Fig. 4).

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Regarding claim 44, Fig. 3 of Kieturakis discloses a first cable (27a) attached to at least a first section of the plurality of sections (21) and disposed in a passage (26a) in at least a second section (22) of the plurality of sections, and arranged for moving the first section with respect to a second section when the first cable is pulled in a proximal direction (as tension is applied to tensioning members), the first cable being offset from a longitudinal axis of the shaft in a first direction (as shown in Fig. 5).

Regarding claim 45, Fig. 5 of Kieturakis discloses a second cable (27b) offset from the longitudinal axis in a second direction, for returning the retractor to the first position (upon release of tension).

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Cuschieri et al. (U.S. Publication Number 2002/0111536) discloses a retractor with multiple segments that can be moved into a closed ring structure.

Kuzmak (U.S. Patent Number 5,522,788) discloses a laparoscopic dissector that can produce a desired curvature.

Beane et al. (U.S. Patent Number 5,976,075) discloses an endoscope system including a shaft member that can be moved into a deflected position.

McMahon et al. (U.S. Patent Number 5,467,763) discloses an instrument with a plurality of segments which can be brought into a bent second position.

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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVANIE DUFOUR whose telephone number is (571)270-7843. The examiner can normally be reached on Mon-Thurs 7:30 a.m.-5:00 p.m., alternate Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Cheng can be reached on 571-272-4433. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./  
Examiner, Art Unit 4115

/Joe H Cheng/  
Supervisory Patent Examiner  
Art Unit 4115